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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,546	05/02/2002	Dan L. Eaton	P3230R1C001-168	1060

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KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 MAIN STREET
IRVINE, CA 92614

EXAMINER

DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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12/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/063,546

Applicant(s)

EATON ET AL.

Examiner

Patricia A. Duffy

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2007</u> | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

The response filed 7-18-07 has been entered into the record.

Rejections Maintained

Claims 1-5 stand rejected under 35 U.S.C. 102(a) as being anticipated by Barnes (WO 00/18904, published 06 April 2000) for reasons made of record.

Applicants' arguments have been carefully considered but are still not persuasive.

Applicants insist that a showing under 37 CFR 1.131 is not needed to demonstrate that Applicants had the invention prior to the cited relevant art and argue that the provisional document provided and argued by Applicants establishes possession of the invention prior to the date of the 102(a) cited art, even in view of the disclaimer of priority to the priority document at issue. While the document can be used as evidence, Applicants again err in insisting that the argued evidence, and not properly attested under 37 CFR 1.131 by the inventors is sufficient to drop the rejection under 102(a). Applicant is directed to MPEP 2132.01 37 CFR 1.131 AFFIDAVIT CAN BE USED TO OVERCOME A 35 U.S.C. 102(a) REJECTION When the reference is not a statutory bar under 35 U.S.C. 102(b), (c), or (d), applicant can overcome the rejection by swearing back of the reference through the submission of an affidavit under 37 CFR 1.131. *In re Foster*, 343 F.2d 980, 145 USPQ 166 (CCPA 1965). If the reference is disclosing applicant's own work as derived from him or her, applicant may submit either a 37 CFR 1.131 affidavit to antedate the reference or a 37 CFR 1.132 affidavit to show derivation of the reference subject matter from applicant and invention by applicant. *In re Facius*, 408 F.2d 1396, 161 USPQ 294 (CCPA 1969). See MPEP § 715 for more information on when an affidavit under 37 CFR 1.131 can be used to overcome a reference and what evidence is required. This is again not persuasive, argument and evidence presented by Applicants representative, in the absence of a properly executed and attested affidavit by the inventors in proper declaratory

form remains not persuasive. Stemple describes sufficiency of a declaration filed under 37 CFR 1.131. NO 1.131 declaration has been filed in this application. Applicant's reliance on the Stemple Doctrine and In re Moore is again not persuasive. Applicant's representative assertions and argument regarding the provisional document cannot replace a properly executed affidavit. The examiner is well aware of that which is required to establish a prior executed invention. Applicants have not put the argued evidence in proper form and attested to by the inventors. Applicants' representative cannot attest to prior invention. The inventors must attest to prior invention. APPLICANTS HAVE NOT FILED A DECLARATION PURSUANT TO 37 CFR 1.131. Applicants' representative, wants to extend the Stemple doctrine to evidence not in affidavit format. Neither Stemple or Moore provide for evidence in the absence of a properly executed affidavit under 37 CFR 1.131. This remains not persuasive, Applicants representatives cannot attest to prior invention and again Applicants have not provided a declaration. Reliance on the facts in Moore and Stemple are therefore inappropriate. In the absence of a properly executed affidavit, the argued evidence of prior invention is not persuasive to remove a reference under 102(a).

Applicants argue that the antibodies of the prior art do not expressly or inherently disclose the claimed invention because the sequences of the polypeptide are not 100% identical and any differences can change antibody binding. This is again not persuasive. The polypeptides have extensive regions of 100% identity. Antibodies made against the whole polypeptide would necessarily bind the regions of identity. The smallest region that an antibody binds is 6 consecutive amino acids (Harlow et al). The polypeptides share 100% identity over 400 consecutive amino acids. Applicants again argue any change to the polypeptide would not produce antibodies that bind the same polypeptide and that these changes would not necessarily lead to an antibody that bound SEQ ID NO:38 This is again not persuasive for reasons previously made of record. One skilled in the immunological

arts would not interpret "specifically binds" as exclusive binding as, as evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586) and Bendayan (J. Histochem. Cytochem. 1995; 43:881-886). That an antibody "cross-reacts", i.e., binds to more than one protein sequence, does not mean that the antibody does not "specifically react" with both proteins. For example, Bost et al. describe antibodies which "cross-react" with IL-2 and HIV envelope protein, but establish that the binding of each protein is due to the presence of a homologous sequence in each protein in which 4 of 6 residues were identical (see entire document, but especially the Abstract and Discussion). Antibodies which bound either the HIV or IL-2 derived sequence did not cross react with irrelevant peptides (e.g., "Results, page 579). Similarly, Bendayan characterizes the specific reactivity of a monoclonal antibody produced to human proinsulin and shows that although the antibody is highly specific; it is nevertheless able to bind to not only human proinsulin, but to proinsulin from other species and even a distinct protein, glucagon, based upon conservation of an Arg-Arg dipeptide sequence in each of these molecules (see entire document). Bendayan concludes that "an antibody directed against such a sequence, although still yielding specific labeling, could reveal different molecules not related to the original antigen" (page 886, last paragraph). See also U.S. Pat. No. 6210670 (Berg) entitled "Cross-Reacting Monoclonal Antibodies Specific for E-Selectin and P-selectin". Applicant's argument attempts to limit the term "specifically reacts" in a manner inconsistent with the well-known and art-recognized specificity of antibody interaction with epitopes defined by particular amino acid sequences. Consequently, it was well known in the art at the time the invention was made that antibody binding of distinct proteins was indeed specific and that the regions between the protein of the prior art and the protein of SEQ ID NO:38 define cross-reactive epitopes on the proteins. Therefore, despite differences, these regions of 100% identity provide for cross-reactive antibodies and cross-reactive antibodies are specific. The extrinsic evidence supports the

conclusions that the antibody of the prior art necessarily and inherently binds SEQ ID NO:38. Applicants argue facts not relied upon by the examiner. The relied upon facts are set forth again. *The examiner will not affirm facts not relied upon to make the rejection, nor references to rejections not made in this application.* Applicants argue all the case law and reiterate that the examiner has not established a prima facie case of inherency because the characteristic of specifically binding to SEQ ID NO:38 does not necessarily flow. This is again not persuasive, because the examiner has established that antibody binding requires a peptide of at least 6 amino acids, that the polypeptides have a region of 400 consecutive amino acids that are 100% identical and that cross-reactive antibodies bind in a specific manner, defined by common epitopes and bind distinct proteins. Therefore, it is maintained that the antibodies of the prior art inherently specifically bind the polypeptide of SEQ ID NO:38. It was well established in the art at the time the invention was made that antibodies raised to one polypeptide would also specifically bind other polypeptides sharing the epitope recognized by the antibody. For example, Bost et al. (Immunol. Invest. 1988; 17:577-586) teach that an antibody specifically bound an epitope shared by two different polypeptides, but did not bind irrelevant peptides not sharing this epitope. The epitope was determined to be a homologous sequence in the two proteins in which 4 of 6 residues were identical (see entire document, but especially the Abstract, Discussion, and "Results", page 579). Similarly, Bendayan (J. Histochem. Cytochem. 1995; 43:881-886) characterized the specific reactivity of a monoclonal antibody produced to human proinsulin and showed that although the antibody was highly specific, it bound to not only human proinsulin, but to proinsulin from other species (see entire document).

The rejection is maintained.

Status of Claims

Claims 1-5 stand rejected.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Shanon Foley can be reached on 571-272-0898.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Patricia A. Duffy

Primary Examiner

Art Unit 1645